

NOTICE: Proposed rule 4731-11-01 has been revised

On August 28, 2018, the Medical Board filed a revised version of proposed rule 4731-11-01 with the Joint Committee on Agency Rule Review ("JCARR"). The rule is revised at paragraph (L) by the addition of the underlined wording set out below:

(L) "Acute pain" means pain that normally fades with healing, is related to tissue damage, significantly alters a patient's typical function and is expected to be time limited and not more than six weeks in duration.

The underlined language was included in the version of the proposed rule when it was filed at the Common Sense Initiative Office. However, it was inadvertently omitted during preparation for the original filing at JCARR.

4731-11-01 **Definitions.**

As used in Chapter 4731-11 of the Administrative Code:

- (A) "Controlled substance" means a drug, compound, mixture, preparation, or substance included in schedule I, II, III, IV, or V pursuant to the provisions of Chapter 3719. of the Revised Code.
- (B) "Controlled substance stimulant" means any drug, compound, mixture, preparation, or substance which is classified as a stimulant in controlled substance schedule II, III, or IV listed in section 3719.41 of the Revised Code, or which is classified as a stimulant in controlled substances schedule II, III, or IV pursuant to section 3719.43 or 3719.44 of the Revised Code.
- (C) "Cross-coverage" means an agreement between an Ohio-licensed physician and another Ohio licensed physician or healthcare provider acting within the scope of their professional license under which the physician provides medical services for an active patient, as that term is defined in paragraph (D) of rule this rule, of the other physician or healthcare provider who is temporarily unavailable to conduct the evaluation of the patient.
- (1) This type of agreement includes on-call coverage for after hours and weekends.
- (2) The medical evaluation required by paragraph (C) of rule 4731-11-09 of the Administrative Code may be a limited evaluation conducted through interaction with the patient.
- (D) For purposes of paragraph (D) of rule 4731-11-09 of the Administrative Code, "active patient" as that term is used in paragraph (C) of this rule, means that within the previous twenty-four months the physician or other healthcare provider acting within the scope of their professional license conducted at least one in-person medical evaluation of the patient or an evaluation of the patient through the practice of telemedicine as that term is defined in 21 C.F.R. 1300.04, in effect as of the effective date of this rule.
- (E) "Utilize a controlled substance or controlled substance stimulant" means to prescribe, administer, dispense, supply, sell or give a controlled substance or controlled substance stimulant.
- (F) "Recognized contraindication" means any contraindication to the use of a drug which is listed in the United States food and drug administration (hereinafter, "F.D.A.") approved labeling for the drug, or which the board determines to be accepted as a contraindication.

- (G) "The board" means the state medical board of Ohio.
- (H) "BMI" means body mass index, calculated as a person's weight in kilograms divided by height in meters squared.
- (I) "Physician" means an individual holding a certificate under Chapter 4731. of the Revised Code to practice medicine and surgery, osteopathic medicine and surgery, or podiatric medicine and surgery and practicing within his or her scope of practice as defined by section 4731.51 of the Revised Code.
- (J) "Board certified addictionologist or addiction psychiatrist" means a medical doctor or doctor of osteopathic medicine and surgery who holds one of the following certifications:
- (1) Subspecialty board certification in addiction psychiatry from the american board of psychiatry and neurology;
 - (2) Board certification in addiction medicine from the american board of addiction medicine;
 - (3) Certification from the American society of addiction medicine;
 - (4) Subspecialty certification in addiction medicine from the American board of preventive medicine; or
 - (5) Board certification with additional qualification in addiction medicine from the American osteopathic association.
- (K) "Office based opioid treatment", or "OBOT", means treatment of opioid addiction utilizing a schedule III, IV or V controlled substance narcotic.
- (L) "Acute pain" means pain that normally fades with healing, is related to tissue damage, significantly alters a patient's typical function and is expected to be time limited and not more than six weeks in duration.
- (M) "Minor" has the same meaning as in section 3719.061 of the Revised Code.
- (N) "Morphine equivalent daily dose (MED)" means a conversion of various opioid analgesics to a morphine equivalent dose by the use of accepted conversion tables provided by the state of Ohio board of pharmacy at: <https://www.ohiopmp.gov/> (effective 2017).
- (O) "Extended-release or long-acting opioid analgesic" means an opioid analgesic that:

- (1) Has United States food and drug administration approved labeling indicating that it is an extended-release or controlled release formulation;
 - (2) Is administered via a transdermal route; or
 - (3) Contains methadone.
- (P) “Opioid analgesic” has the same meaning as in section 3719.01 of the Revised Code and means a controlled substance that has analgesic pharmacologic activity at the opioid receptors of the central nervous system, including but not limited to the following drugs and their varying salt forms or chemical congeners: buprenorphine, butorphanol, codeine (including acetaminophen and other combination products), dihydrocodeine, fentanyl, hydrocodone (including acetaminophen combination products), hydromorphone, meperidine, methadone, morphine sulfate, oxycodone (including acetaminophen, aspirin, and other combination products), oxymorphone, tapentadol, and tramadol.
- (Q) “Hospice care program” has the same meaning as in section 3712.01 of the Revised Code.
- (R) “Palliative care” has the same meaning as in section 3712.01 of the Revised Code.
- (S) “Terminal condition” has the same meaning as in section 2133.01 of the Revised Code.
- (T) “Medication therapy management” has the same meaning as in rule 4729:5-12-01 of the Administrative Code.
- (U) “Subacute pain” means pain that has persisted after reasonable medical efforts have been made to relieve it and continues either episodically or continuously for more than six weeks but less than twelve weeks following initial onset of pain. It may be the result of underlying medical disease or condition, injury, medical or surgical treatment, inflammation, or unknown cause.
- (V) Chronic pain” means pain that has persisted after reasonable medical efforts have been made to relieve it and continues either episodically or continuously for twelve or more weeks following initial onset of pain. It may be the result of an underlying medical disease or condition, injury, medical treatment, inflammation, or unknown cause.

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4731-11-02

General provisions.

- (A) A physician shall not utilize a controlled substance other than in accordance with all of the provisions of this chapter of the Administrative Code.
- (B) A physician shall not utilize a controlled substance without taking into account the drug's potential for abuse, the possibility the drug may lead to dependence, the possibility the patient will obtain the drug for a nontherapeutic use or to distribute to others, and the possibility of an illicit market for the drug.
- (C) A physician shall complete and maintain accurate medical records reflecting the physician's examination, evaluation, and treatment of all the physician's patients. Patient medical records shall accurately reflect the utilization of any controlled substances in the treatment of a patient and shall indicate the diagnosis and purpose for which the controlled substance is utilized, and any additional information upon which the diagnosis is based.
- (D) A physician shall obey all applicable provisions of sections 3719.06, 3719.07, 3719.08 and 3719.13 of the Revised Code and the rules promulgated thereunder, ~~rules 4729-5-30 and 4729-5-13 of the Administrative Code,~~ all prescription issuance rules adopted under chapter 4729. of the Revised Code, and all applicable provisions of federal law governing the possession, distribution, or use of controlled substances.
- (E) Violations of this rule:
- (1) A violation of any provision of this rule, as determined by the board, shall constitute any or all of the following: "failure to maintain minimal standards applicable to the selection or administration of drugs," as that clause is used in division (B)(2) of section 4731.22 of the Revised Code; and "a departure from, or the failure to conform to, minimal standards of care of similar physicians under the same or similar circumstances, whether or not actual injury to a patient is established," as that clause is used in division (B)(6) of section 4731.22 of the Revised Code.
 - (2) A violation of paragraph (C) of this rule shall further constitute "selling, prescribing, giving away, or administering drugs for other than legal and legitimate therapeutic purposes," as that clause is used in division (B)(3) of section 4731.22 of the Revised Code.

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4731-11-14

Prescribing for subacute and chronic pain.

- (A) Prior to treating, or continuing to treat subacute or chronic pain with an opioid analgesic, the physician shall first consider and document non-medication and non-opioid treatment options.
- (1) If opioid analgesic medications are required as determined by a history and physical examination, the physician shall prescribe for the minimum quantity and potency needed to treat the expected duration of pain and improve the patient's ability to function.
 - (2) The physician shall comply with the requirements of rule 4731-11-02 of the Administrative Code.
- (B) Before prescribing an opioid analgesic for subacute or chronic pain, the physician shall complete or update and document in the patient record assessment activities to assure the appropriateness and safety of the medication including:
- (1) History and physical examination including review of previous treatment and response to treatment, patient's adherence to medication and non-medication treatment, and screening for substance misuse or substance use disorder;
 - (2) Laboratory or diagnostic testing or documented review of any available relevant laboratory or diagnostic test results. If evidence of substance misuse or substance use disorder exists, diagnostic testing shall include urine drug screening;
 - (3) Review the results of an OARRS check in compliance with rule 4731-11-11 of the Administrative Code;
 - (4) A functional pain assessment which includes the patient's ability to engage in work or other purposeful activities, the pain intensity and its interference with activities of daily living, quality of family life and social activities, and the physical activity of the patient;
 - (5) A treatment plan based upon the clinical information obtained, to include all of the following components:
 - (a) Diagnosis;
 - (b) Objective goals for treatment;
 - (c) Rationale for the medication choice and dosage; and

- (4) Except when the patient was prescribed an average daily dosage that exceeded fifty MED before the effective date of this rule, the physician shall document consideration of the following:
- (a) Consultation with a specialist in the area of the body affected by the pain;
 - (b) Consultation with a pain management specialist;
 - (c) Obtaining a medication therapy management review by a pharmacist; and
 - (d) Consultation with a specialist in addiction medicine or addiction psychiatry, if aberrant behaviors indicating medication misuse or substance use disorder are noted.
- (5) The physician shall consider offering a prescription for naloxone to mitigate risk of overdose.
- (D) Prior to increasing the opioid dosage to a daily average of eighty MED or greater, the physician shall complete all of the following:
- (1) Enter into a written pain treatment agreement with the patient that outlines the physician's and patient's responsibilities during treatment and requires the patient or patient guardian's agreement to all of the following provisions:
 - (a) Permission for drug screening and release to speak with other practitioners concerning the patient's condition or treatment;
 - (b) Cooperation with pill counts or other checks designed to assure compliance with the treatment plan and to minimize the risk of misuse or diversion;
 - (c) The understanding that the patient shall only receive opioid medications from the physician treating the chronic pain unless there is written agreement among all of the prescribers of opioids outlining the responsibilities and boundaries of prescribing for the patient; and
 - (d) The understanding that the dosage may be tapered if not effective or if the patient does not abide by the treatment agreement.
 - (2) Offer a prescription for naloxone to the patient as described in paragraph (B) of this rule.
 - (3) Except when the patient was prescribed an average daily dosage that exceeded eighty MED before the effective date of this rule, obtain at least one of the following based upon the patient's clinical presentation:

- (a) Consultation with a specialist in the area of the body affected by the pain;
 - (b) Consultation with a pain management specialist;
 - (c) Obtain a medication therapy management review; or
 - (d) Consultation with a specialist in addiction medicine or addiction psychiatry if aberrant behavior indicating medication misuse or substance use disorder may be present.
- (E) The physician shall not prescribe a dosage that exceeds an average of one hundred twenty MED per day. This prohibition shall not apply in the following circumstances:
 - (1) The physician holds board certification in pain medicine;
 - (2) The physician has received a written recommendation for a dosage exceeding an average of one hundred twenty MED per day from a board certified pain medicine physician who based the recommendation on a face-to-face visit and examination of the patient. The prescribing physician shall maintain the written recommendation in the patient's record; or
 - (3) The patient was receiving an average daily dose of one hundred twenty MED or more prior to the effective date of this rule. The physician shall follow the steps in paragraph (E)(2) prior to escalating the patient's dose.
- (F) During the course of treatment with an opioid analgesic at doses below the average of fifty MED per day, the physician shall provide periodic follow-up assessment and documentation of the patient's functional status, the patient's progress toward treatment objectives, indicators of possible addiction, drug abuse or drug diversion and the notation of any adverse drug effects.
- (G) During the course of treatment with an opioid analgesic at doses at or above the average of fifty MED per day, the physician shall complete and document in the patient record the following no less than every three months:
 - (1) Review of the course of treatment and the patient's response and adherence to treatment.
 - (2) The assessment shall include a review of any complications or exacerbation of the underlying condition causing the pain through appropriate interval history, physical examination, any appropriate diagnostic tests, and specific treatments to address the findings.

- (3) The assessment of the patient's adherence to treatment including any prescribed non-pharmacological and non-opioid treatment modalities;
- (4) Rationale for continuing opioid treatment and nature of continued benefit, if present.
- (5) The results of an OARRS check in compliance with rule 4731-11-11 of the Administrative Code.
- (6) Screening for medication misuse or substance use disorder. Urine drug screen should be obtained based on clinical assessment of the physician with frequency based upon presence or absence of aberrant behaviors or other indications of addiction or drug abuse.
- (7) Evaluation of other forms of treatment and the tapering of opioid medication if continued benefit cannot be established.
- (H) This rule does not apply to the physician who prescribes an opioid in any of the following situations:

 - (1) The medication is for a patient in hospice care.
 - (2) The patient has terminal cancer or another terminal condition, as that term is defined in section 2133.01 of the Revised Code.
- (I) This rule does not apply to inpatient prescriptions as defined in Chapter 4729. of the Revised Code.

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